December 18, 2024

ETEX Corporation
Priti Dhabekar
Regulatory Affairs Sr Specialist
55 Messina Drive
Braintree, Massachusetts 02184

Re: K243609
Trade/Device Name: EquivaBone Osteoinductive Bone Graft Substitute (EquivaBone)
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: November 21, 2024
Received: November 22, 2024

Dear Priti Dhabekar:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JESSE MUIR -S Digitally signed by JESSE MUIR -S
Date: 2024.12.18 14:34:20 -05'00'

Jesse Muir, PhD
Assistant Director
DHT6C: Division of Restorative, Repair & Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243609

Device Name

EquivaBone Osteoinductive Bone Graft Substitute (EquivaBone)

Indications for Use *(Describe)*

EquivaBone is a bone graft substitute that combines synthetic calcium phosphate and demineralized bone. It is resorbed and replaced with new bone during the healing process. It is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e. posterolateral spine) and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K243609

510(k) Summary

Prepared on: 2024-12-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ETEX Corporation
Applicant Address	55 Messina Drive Braintree MA 02184 United States
Applicant Contact Telephone	8625919661
Applicant Contact	Ms. Priti Dhabekar
Applicant Contact Email	priti.dhabekar@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	EquivaBone Osteoinductive Bone Graft Substitute (EquivaBone)
Common Name	Resorbable calcium salt bone void filler device
Classification Name	Filler, Bone Void, Calcium Compound
Regulation Number	888.3045
Product Code(s)	MQV, MBP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K101557	EquivaBone Osteoinductive Bone Graft Substitute	MQV , MBP
K082793	InterGro DBM (Putty, Paste, Plus)	MQV, MBP, GXP

Device Description Summary

21 CFR 807.92(a)(4)

EquivaBone is a biocompatible bone graft substitute material consisting of Calcium Phosphate (CaP3), Carboxymethylcellulose (CMC) and Demineralized Bone Matrix (DBM). EquivaBone is supplied in a single use kit as sterile powders and hydration solution that are mixed together at the time of use in the operating room to form flowable putty which is implanted manually or can be extruded through a syringe. After implantation the product hardens at body temperature and resorbs and remodels during the healing process.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

EquivaBone is a bone graft substitute that combines synthetic calcium phosphate and demineralized bone. It is resorbed and replaced with new bone during the healing process. It is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e. posterolateral spine) and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device are identical to the primary predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device has similar technological characteristics as the primary predicate system.

Demineralized Bone Matrix (DBM) Source:
The proposed modification will transition DBM sourcing from AlloSource to LifeLink.
The comparison of the DBM from both sources is based on the chemical composition, physical properties and performance characteristics of the DBM. In each comparison, we have determined that the DBM sourced from LifeLink Tissue Bank is equivalent to the DBM sourced from AlloSource.

Osteoinductive Potential:
The proposed alternative assay test method C2C12 will be employed for determining osteoinductivity. A correlation study was conducted to validate the C2C12 assay results against the current in vivo testing in place for the predicate device. This validation established a pass/fail threshold that correlated with the current pass/fail threshold for the predicate device, that of an in vivo osteoinduction (OI) score of 1.
The in vitro C2C12 OI assay test results correlate with the athymic rat implantation assay, demonstrating linear correlation ($m = 0.0997$) with correlation coefficient ($R^2 = 0.9204$), meeting the required acceptance criteria for the method ($R2 \geq 0.8$).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Tests/Justifications:
- Full Conversion
- Injectability
- Washout Resistance
- Compressive Strength and Dimensional Stability
- Relative Paste Hardness
- Setting pH and Temperature
- Mass-to-Volume Ratio
- User Testing
- Porosity Testing

- Osteoinductive Potential- C2C12 Assay

Animal and Clinical Tests:
- None provided